**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| NOVARTIS AG, NOVARTIS PHARMACEUTICALS CORPORATION,<br><br>Plaintiffs,<br><br>v.<br><br>NOVADOZ PHARMACEUTICALS LLC, MSN PHARMACEUTICALS INC., and MSN LABORATORIES PRIVATE LIMITED,<br><br>Defendants. | Civil Action No. 25-849 |

**DECLARATION OF STEPHEN VALAZZA IN SUPPORT OF PLAINTIFFS' ORDER TO SHOW CAUSE FOR A TEMPORARY RESTRAINING ORDER AND MOTION FOR A PRELIMINARY INJUNCTION**

I, Stephen Valazza, hereby declare as follows:

1. I am Technical Project Leader at Novartis Pharmaceuticals Corporation (together with Novartis AG, "Novartis"). I am over the age of 18 and am competent to testify. I submit this declaration in support of Plaintiffs' Order to Show Cause for a Temporary Restraining Order and Motion for a Preliminary Injunction. The facts stated herein are based on my personal knowledge and on my review of Novartis's records and information in the public domain.

**Professional Background**

2. I have worked at Novartis Pharmaceuticals Corporation since its founding in 1996. Before that, I worked at Ciba-Geigy, a predecessor to Novartis, for five years.

3. I have a Bachelor of Science in Pharmacy from the University of the Sciences in Philadelphia. I am a registered pharmacist by the New Jersey Board of Pharmacy.

4. I have worked as a Technical Project Leader in the Technical Research and Development ("TRD") group at Novartis for more than 10 years. TRD is responsible for developing new drugs and preparing them for commercial production, including developing the final form of the drug that will be offered to consumers.

5. As a Technical Project Leader, I lead a development team that is focused on the formulation development, process development, technical transfer and scale-up for Novartis Pharmaceuticals Corporation. I have worked on the formulation of numerous Novartis products, including Entresto. In recent years, I have specialized in leading the formulation and technical development of malaria drugs and other global health products.

6. Prior to my transition into the role as Technical Project Leader, I worked as a Drug Product Project Leader and Formulation Expert where I gained significant knowledge and experience in formulation and process development of solid dosage forms.

**Novartis Tablet Design**

7. Each Novartis tablet goes through a multi-phase product design process that involves stakeholders from several Novartis groups, including Legal, Marketing, Clinical Development, Regulatory Affairs, TRD, and Technical Operations. This process covers every step of drug development leading to the commercial sale of the pharmaceutical.

8. During the design process, TRD will run tests to determine the ways it can formulate a pharmaceutical without affecting its stability. For example, a drug may be formulated as a film-coated tablet, a capsule, a powder or a liquid, among other options.

9. Once appropriate formulations are identified, members of Novartis's product design team, including Marketing, will choose the form for the medication based on both regulatory factors as well as marketability and consumer preference. For example, a liquid form may be chosen if the target consumer is a child.

10. The product design process also includes choosing a color for the product. For film-coated tablets like Entresto, Novartis has developed a proprietary color palette of 23 options. If TRD determines that coloring does not impact the stability of the drug, the product design team can choose from these 23 options when designing the appearance of the drug. This choice is typically driven by commercial factors, including the desire to differentiate Novartis's products from those of competitors.

11. Aside from color, the process design team will also choose the shape of a film-coated tablet. At Novartis, we typically use one of six different shapes for tablets: round flat, round curved, elongated flat, elongated curved, ovaloid flat, and ovaloid curved. As with color, once TRD determines that a tablet format is viable for a certain pharmaceutical, the decision of what shape to use is largely driven by commercial factors (such as product differentiation).

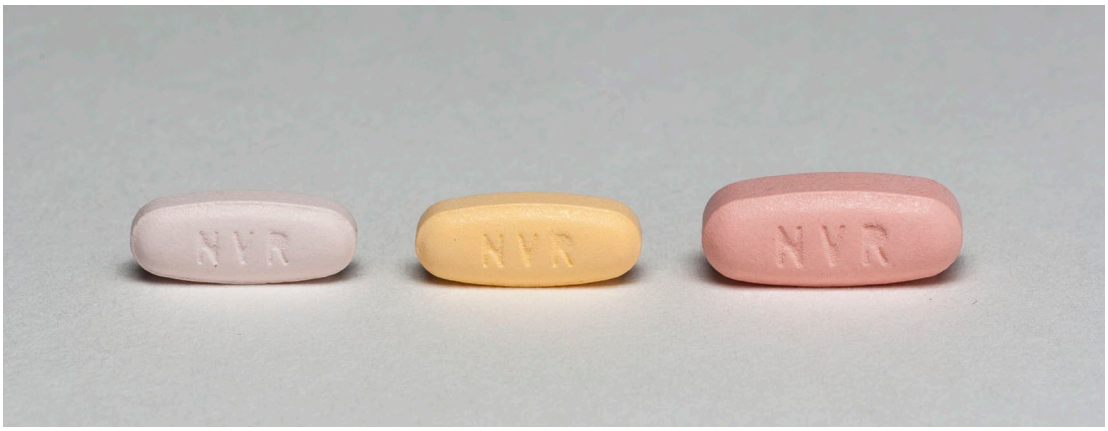
12. The size of a tablet is also part of the product design process. A pharmaceutical tablet typically has a minimum size based on its formulation and compressibility. However, that minimum size can be increased to meet certain aesthetic goals. For example, a tablet size may be increased to make it uniform with other tablets in the same family of drugs.

**Entresto's Distinctive Appearance**

13. Entresto is a Novartis prescription medicine.

14. Entresto is offered in three doses in the United States. Each dose is offered as a film coated tablet.

15. As shown below, the 24/26 mg dose is an ovaloid, violet white tablet measuring 13.1 mm x 5.2 mm (the "Low Starting Dose"); the 49/51 mg dose is an ovaloid, pale yellow tablet measuring 13.1 mm x 5.2 mm (the "Recommended Starting Dose"); and the 97/103 mg dose is an ovaloid, light pink tablet measuring 15.1 mm x 6.0 mm (the "Target Dose").




16. The appearance of the Entresto tablets was chosen to differentiate the tablets from competitors' trade dress.

17. The violet white, pale yellow, and light pink colors of the tablets were chosen from the Novartis color palette described above. With respect to Entresto, the colors of the pills did not impact the stability of the drug. Instead, when designing Entresto, the product design team had the option of any of the 23 colors from the Novartis color palette. The selection of violet white, pale yellow, and light pink was unrelated to function or efficacy.

18. The product design team also chose an "ovaloid" shape for the Entresto tablets to differentiate them from competitors' tablets.

19. Entresto could have been offered in other shapes. In fact, I was personally involved in the activities to change the shape of the lowest dose of the Entresto pill during the development phase from a round shape to an ovaloid shape. This change was requested by Marketing to match the higher doses of Entresto, which were already in an ovaloid shape.

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20. Finally, I am not aware of any functional reason why the Low Starting Dose and the Recommended Starting Dose need to be smaller than the Target Dose. These sizes could be made uniform without impacting the efficacy of the formulation.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 30th day of January, 2025, in East Hanover, N.J.

Stephen Valazza